

We Claim:

1. An immune modulation device that is suitable for use in modulating an immune response in animals, comprising an impermeable biocompatible shell having an outer surface with plurality of pores of suitable size to allow the ingress and egress of immune cells and said impermeable biocompatible shell having an interior lumen, a biocompatible fibrous scaffolding being disposed within said interior lumen.
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2. The immune modulation device of claim 1 wherein the fibrous scaffolding has a porosity of from about 25 percent to about 95 percent.
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3. The immune modulation device of claim 1 wherein the fibrous scaffolding is made from filaments with a diameter of less than 20 microns.
4. The immune modulation device of claim 1 wherein the fibrous scaffolding is made from filaments with a denier of from about 0.2 to about 10.
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5. The immune modulation device of claim 1 wherein the fibrous scaffolding is made from filaments with a denier of from about 0.8 to about 6.
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6. The immune modulation device of claim 1 wherein the fibrous scaffolding is made from a bundle of filaments having a total denier of from about 20 to about 400 denier.
7. The immune modulation device of claim 1 wherein the fibrous scaffold is made from a textured yarn.
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8. The immune modulation device of claim 7 wherein the textured yarn is selected from the group consisting of bulked yarns, coil yarns, core bulked yarns, crinkle yarns, entangled yarns, modified stretch yarns, nontorqued yarns, set yarns, stretch yarns and torqued yarns and combinations thereof.
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9. The immune modulation device of claim 1 wherein the immune modulation device has a three dimensional shape selected from the group consisting of spherical, cylindrical, rectangular and rhomboidal.

5 10. The immune modulation device of claim 8 wherein the immune modulation device is cylindrical in shape.

11. The immune modulation device of claim 10 wherein the cylindrically shaped immune modulation device has an outer diameter of less than 1 millimeter.

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12. The immune modulation device of claim 11 wherein the cylindrically shaped immune modulation device has an outer diameter of less than 750 microns.

13. The immune modulation device of claim 10 wherein the cylindrically shaped immune modulation device has a wall thickness of less than 250 microns.

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14. The immune modulation device of claim 13 wherein the cylindrically shaped immune modulation device has a wall thickness of less than 150 microns.

20 15. The immune modulation device of claim 1 wherein the pores on the outer surface of the immune modulation device comprise less than 25 percent of the outer surface.

16. The immune modulation device of claim 15 wherein the pores range in size 25 from about 10 to about 500 microns.

17. The immune modulation device of claim 1 wherein the immune modulation device is bioabsorbable.

30 18. The immune modulation device of claim 17 wherein the bioabsorbable immune modulation device is made from a polymer selected from the group consisting of aliphatic polyesters, poly(amino acids), copoly(ether-esters), polyalkylenes oxalates, polyamides, tyrosine derived polycarbonates, poly(iminocarbonates), polyorthoesters,

polyoxaesters, polyamidoesters, polyoxaesters containing amine groups, poly(anhydrides), polyphosphazenes, biomolecules and blends thereof.

19. The immune modulation device of claim 18 wherein the bioabsorbable immune
5 modulation device is made from an aliphatic polyester.

20. The immune modulation device of claim 19 wherein the aliphatic polyester is selected from the group consisting of homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso lactide), glycolide (including glycolic acid), ε-
10 caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, delta-valerolactone, beta-butylolactone, gamma-butylolactone, ε-decalactone, hydroxybutyrate, hydroxyvalerate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one, 2,5-diketomorpholine,
15 pivalolactone, gamma, gamma-diethylpropiolactone, ethylene carbonate, ethylene oxalate, 3-methyl-1,4-dioxane-2,5-dione, 3,3-diethyl-1,4-dioxan-2,5-dione, 6,8-dioxabicyclooctane-7-one and polymer blends thereof.

21. The immune modulation device of claim 20 wherein the shell is made from an
20 aliphatic polyester selected from the group consisting of homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso lactide), glycolide (including glycolic acid), ε-caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one and polymer blends thereof.
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22. The immune modulation device of claim 20 wherein the shell is made from an aliphatic polyester selected from the group consisting of poly(p-dioxanone), glycolide-co-ε-caprolactone, glycolide-co-trimethylene carbonate, glycolide-co-1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one and blends thereof.
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23. The immune modulation device of claim 1 wherein the biocompatible fibrous scaffolding is made from an aliphatic polyester selected from the group consisting of

homopolymers and copolymers of lactide (which includes lactic acid, D-, L- and meso-lactide), glycolide (including glycolic acid), ϵ -caprolactone, p-dioxanone (1,4-dioxan-2-one), trimethylene carbonate (1,3-dioxan-2-one), alkyl derivatives of trimethylene carbonate, 1,4-dioxepan-2-one (including its dimer 1,5,8,12-tetraoxacyclotetradecane-5,7,14-dione), 1,5-dioxepan-2-one, 6,6-dimethyl-1,4-dioxan-2-one and polymer blends thereof.

24. The immune modulation device of claim 23 wherein the biocompatible fibrous scaffolding is made from an aliphatic polyester selected polyglycolide, poly(p-dioxanone), glycolide-co- ϵ -caprolactone, glycolide-co-trimethylene carbonate and glycolide-co-lactide.

25. The immune modulation device of claim 1 wherein the shell is made from poly(p-dioxanone) and the fibrous scaffolding is made from a copolymer of about 90 weight percent glycolide and about 10 weight percent lactide.

26. The immune modulation device of claim 25 wherein the fibrous scaffolding is made from a textured yarn.

27. The immune modulation device of claim 1 wherein the shell is made from a copolymer of from about 35 to about 45 weight percent epsilon-caprolactone and from about 55 to about 65 weight percent glycolide and the fibrous scaffolding is made from a copolymer of about 90 weight percent glycolide and about 10 weight percent lactide.

28. The immune modulation device of claim 27 wherein the fibrous scaffolding is made from a textured yarn.

29. The immune modulation device of claim 1 which contains one or more antigens.

30. The immune modulation device of claim 29 wherein the antigen is selected from the group of natural antigens, synthetic antigens and combinations thereof.

31. The immune modulation device of claim 30 wherein the natural antigen is derived from a microbe selected from the group consisting of *Actinobacillus equuli*, *Actinobacillus lignieresii*, *Actinobacillus seminis*, *Aerobacter aerogenes*, *Borrelia burgdorferi*, *Borrelia garinii*, *Borrelia afzelii*, *Babesia microti*, *Klebsiella pneumoniae*,

5 *Bacillus cereus*, *Bacillus anthracis*, *Bordetella pertussis*, *Brucella abortus*, *Brucella melitensis*, *Brucella ovis*, *Brucella suis*, *Brucella canis*, *Campylobacter fetus*, *Campylobacter fetus intestinalis*, *Chlamydia psittaci*, *Chlamydia trachomatis*, *Clostridium tetani*, *Corynebacterium acne* Types 1 and 2, *Corynebacterium diphtheriae*, *Corynebacterium equi*, *Corynebacterium pyogenes*, *Corynebacterium renale*, *Coxiella burnetii*, *Diplococcus pneumoniae*, *Escherichia coli*, *Ehrlichia phagocytophila*, *Ehrlichia equi*, *Francisella tularensis*, *Fusobacterium necrophorum*, *Giardia lamblia*, *Granuloma inguinale*, *Haemophilus influenzae*, *Haemophilus vaginalis*, Group b *Hemophilus ducreyi*, *Lymphopathia venereum*, *Leptospira pomona*, *Listeria monocytogenes*, *Microplasma hominis*, *Moraxella bovis*, *Mycobacterium tuberculosis*, *Mycobacterium laprae*, *Mycoplasma bovigenitalium*, *Neisseria gonorrhoea*, *Neisseria meningitidis*, *Pseudomonas maltophilia*, *Pasteurella multocida*, *Pasteurella haemolytica*, *Proteus vulgaris*, *Pseudomonas aeruginosa*, *Plasmodium berghei*, *Plasmodium falciparum*, *Plasmodium malariae*, *Plasmodium ovale*, *Plasmodium vivax*, *Rickettsia prowazekii*, *Rickettsia mooseri*, *Rickettsia rickettsii*,

10 *Rickettsia tsutsugamushi*, *Rickettsia akari*, *Salmonella abortus ovis*, *Salmonella abortus equi*, *Salmonella dublin*, *Salmonella enteritidis*, *Salmonella heidelberg*, *Salmonella paratyphi*, *Salmonella typhimurium*, *Shigella dysenteriae*, *Staphylococcus aureus*, *Streptococcus ecoli*, *Staphylococcus epidermidis*, *Streptococcus pyogenes*, *Streptococcus mutans*, *Streptococcus Group B*, *Streptococcus bovis*, *Streptococcus dysgalactiae*, *Streptococcus equisimili*, *Streptococcus uberis*, *Streptococcus viridans*, *Treponema pallidum*, *Vibrio cholerae*, *Yersina pesti*, *Yersinia enterocolitica*, *Aspergillus fumigatus*, *Blastomyces dermatitidis*, *Candida albicans* *Cryptococcus neoformans*, *Coccidioides immitis*, *Histoplasma capsulatum*, influenza viruses, HIV, hanta viruses, human papilloma virus, cytomegalovirus, polio virus, rabies virus,

15 *Equine herpes virus*, *Equine arteritis virus*, *IBR--IBP virus*, *BVD--MD virus*, *Herpes virus* (humonis types 1 and 2), *Mumps virus*, *Rubella virus*, *Measles virus*, *Smallpox virus*, *Hepatitis viruses*, *Rift Valley Fever virus*, *viral encephalitises*, *Schistosoma*, *Onchocerca*, parasitic amoebas and combination thereof.

32. A method of modulating the immune system in an animal to an antigen by implanting within the body of said animal an immune modulation device comprising an impermeable biocompatible shell having an outer surface with plurality of pores of suitable size to allow the ingress and egress of immune cells and said impermeable biocompatible shell having an interior lumen, a biocompatible fibrous scaffolding being disposed within said interior lumen, said interior lumen containing a quantity of antigen sufficient to provoke an immune response.

10 33. The method of claim 32 wherein the antigen is bioavailable at the time the immune modulation device is implanted into said animal.

34. The method of claim 32 wherein the antigen becomes bioavailable after the immune modulation device is implanted into said animal.

15 35. The method of claim 32 wherein the quantity of antigen and the timing of the bioavailability of said antigen within the immune modulation device relative to the time of implantation of the immune modulation device into said animal results in inducing or enhancing the immune response to said antigen.

20 36. The method of claim 32 wherein the quantity of antigen and the timing of the bioavailability of said antigen within said immune modulation device relative to the time of implantation of said immune modulation device into said animal is sufficient to result in suppressing or down regulating an existing or potential immune response to said antigen.

25 37. The method of claim 32 wherein multiple antigens are present in the device in amounts sufficient to provoke an immune response.

30 38. The method of claim 32 wherein only a portion of the antigen is bioavailable at a time the immune modulation device is implanted.

39. The method of claim 37 wherein only a portion of the multiple antigens are bioavailable at a time the immune modulation device is implanted.

40. The method of claim 32 wherein only a portion of the antigen is bioavailable at
5 3 days after implantation of the immune modulation device.

41. A method of obtaining immune cells from an animal comprising harvesting
immune cells from an immune modulation device comprised of an impermeable
biocompatible shell having an outer surface with plurality of pores of suitable size to
10 allow the ingress and egress of immune cells and said impermeable biocompatible shell
having an interior lumen, a biocompatible fibrous scaffolding being disposed within
said interior lumen, said interior lumen having therein a quantity of antigen or
chemotactic agent sufficient to provoke an immune response that was implanted within
an animal time sufficient to allow immune cells to migrate into the immune modulation
15 device.

42. The method of claim 41 wherein the harvested cells are reintroduced to animals.

43. A method of manufacturing an immune modulation device having an
impermeable biocompatible shell having an outer surface and an interior lumen
20 comprising

25 placing a fibrous scaffolding within an interior lumen of the impermeable
biocompatible shell; and
forming pores within said biocompatible impermeable shell of suitable size to
allow the ingress and egress of immune cells.

44. The method of claim 43 wherein the biocompatible impermeable shell has a
30 cylindrical shape having a first end and a second end.

45. The method of claim 44 wherein the first end of the biocompatible impermeable
shell is sealed.

46. The method of claim 45 wherein the end is sealed after the fibrous scaffolding is placed within the biocompatible impermeable shell.

5 47. The method of claim 46 wherein the biocompatible impermeable shell is made of a polymer.

48. The method of claim 47 wherein the end of the biocompatible impermeable shell is crimped and heated to seal said first end.

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49. The method of claim wherein 43 wherein at least one antigen is inserted within the interior lumen in an amount sufficient to provoke an immune response.

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50. The immune modulation device of claim 43 wherein the pores are formed by laser ablation.

51. The immune modulation device of claim 43 wherein the impermeable biocompatible shell having an outer surface and an interior lumen is formed by extruding a biocompatible polymer.

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52. The immune modulation device of claim 10 wherein the cylinder has a first end and a second end, said first end being sealed.